110TH CONGRESS
1ST SESSION

S. 251

To amend the Federal Food, Drug, and Cosmetic Act with respect to the importation of prescription drugs, and for other purposes.

IN THE SENATE OF THE UNITED STATES

JANUARY 10, 2007

Mr. VITTER (for himself and Mr. DEMINT) introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

---

A BILL

To amend the Federal Food, Drug, and Cosmetic Act with respect to the importation of prescription drugs, and for other purposes.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the ''Pharmaceutical Market Access Act of 2007''.

SEC. 2. FINDINGS.

Congress finds as follows:

(1) Americans unjustly pay up to 1,000 percent more to fill their prescriptions than consumers in other countries.

(2) The United States is the world's largest market for pharmaceuticals yet consumers still pay the world's highest prices.

(3) An unaffordable drug is neither safe nor effective. Allowing and structuring the importation of prescription drugs ensures access to affordable drugs, thus providing a level of safety to American consumers they do not currently enjoy.

(4) Prescription drug costs are a leading cause of the growth in United States health care spending, which reached nearly $2,000,000,0000 in 2005, of which spending on prescription drugs amounted to $200,700,000,000.

(5) According to the Congressional Budget Office, American seniors alone will spend $1,800,000,000,000 on pharmaceuticals over the next 10 years.

(6) Allowing open pharmaceutical markets could save American consumers at least $635,000,000,000 of their own money.

SEC. 3. PURPOSES.

The purposes of this Act to—

(1) give all Americans immediate relief from the outrageously high cost of pharmaceuticals;

(2) reverse the perverse economics of the American pharmaceutical market;

(3) allow the importation of prescription drugs only if the drugs and facilities where such drugs are manufactured are approved by the Food and Drug Administration, and to exclude pharmaceutical narcotics;

(4) ensure continued integrity to the prescription drug supply of the United States by—

(A) requiring that imported prescription drugs be packaged and shipped using counterfeit-resistant technologies;

(B) requiring Internet pharmacies to register with the United States Government for Americans to verify authenticity before purchases over the Internet;

(C) requiring all foreign sellers to register with United States Government and submit to facility inspections by the Government without prior notice; and

(D) limiting the eligible countries from which prescription drugs may be imported to Canada, member countries of the European

Union, and other highly industrialized nations with safe pharmaceutical infrastructures.

SEC. 4. AMENDMENTS TO SECTION 804 OF THE FEDERAL FOOD, DRUG, AND COSMETIC ACT.

(a) DEFINITIONS.—Section 804(a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 384(a)) is amended to read as follows:

''(a) DEFINITIONS.—In this section:

''(1) IMPORTER.—The term 'importer' means a pharmacy, group of pharmacies, pharmacist, or wholesaler.

''(2) PERMITTED COUNTRY.—The term 'permitted country' means Australia, Canada, Israel, Japan, New Zealand, Switzerland, South Africa, Austria, Belgium, Denmark, Finland, France, Germany, Greece, Ireland, Italy, Luxemburg, Netherlands, Portugal, Spain, Sweden, the United Kingdom, Iceland, Liechtenstein, and Norway, except that the Secretary—

''(A) may add a country, union, or economic area as a permitted country for purposes of this section if the Secretary determines that the country, union, or economic area has a pharmaceutical infrastructure that is substantially equivalent or superior to the pharma-

ceutical infrastructure of the United States, taking into consideration pharmacist qualifications, pharmacy storage procedures, the drug distribution system, the drug dispensing system, and market regulation; and

''(B) may remove a country, union, or economic area as a permitted country for purposes of this section if the Secretary determines that the country, union, or economic area does not have such a pharmaceutical infrastructure.

''(3) PHARMACIST.—The term 'pharmacist' means a person licensed by the relevant governmental authority to practice pharmacy, including the dispensing and selling of prescription drugs.

''(4) PHARMACY.—The term 'pharmacy' means a person that is licensed by the relevant governmental authority to engage in the business of selling prescription drugs that employs 1 or more pharmacists.

''(5) PRESCRIPTION DRUG.—The term 'prescription drug' means a drug subject to section 503(b), other than—

''(A) a controlled substance (as defined in section 102 of the Controlled Substances Act (21 U.S.C. 802));

"(B) a biological product (as defined in section 351 of the Public Health Service Act (42 U.S.C. 262));

"(C) an infused drug (including a peritoneal dialysis solution);

"(D) an intravenously injected drug;

"(E) a drug that is inhaled during surgery; or

"(F) a drug which is a parenteral drug, the importation of which pursuant to subsection (b) is determined by the Secretary to pose a threat to the public health, in which case section 801(d)(1) shall continue to apply.

"(6) QUALIFYING DRUG.—The term 'qualifying drug' means a prescription drug that—

"(A) is approved pursuant to an application submitted under section 505(b)(1); and

"(B) is not—

"(i) a drug manufactured through 1 or more biotechnology processes;

"(ii) a drug that is required to be refrigerated; or

"(iii) a photoreactive drug.

"(7) QUALIFYING INTERNET PHARMACY.—The term 'qualifying Internet pharmacy' means a reg-

istered exporter that dispenses qualifying drugs to individuals over an Internet website.

''(8) QUALIFYING LABORATORY.—The term 'qualifying laboratory' means a laboratory in the United States that has been approved by the Secretary for the purposes of this section.

''(9) REGISTERED EXPORTER.—The term 'registered exporter' means a person that is in the business of exporting a drug to persons in the United States (or that seeks to be in such business), for which a registration under this section has been approved and is in effect.

''(10) WHOLESALER.—

''(A) IN GENERAL.—The term 'wholesaler' means a person licensed as a wholesaler or distributor of prescription drugs in the United States under section 503(e)(2)(A).

''(B) EXCLUSION.—The term 'wholesaler' does not include a person authorized to import drugs under section 801(d)(1).''.

(b) REGULATIONS.—Section 804(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 384(b)) is amended to read as follows:

''(b) REGULATIONS.—Not later than 180 days after the date of enactment of the Pharmaceutical Market Ac-

cess Act of 2007, the Secretary, after consultation with the United States Trade Representative and the Commissioner of the Bureau of Customs and Border Protection, shall promulgate regulations permitting pharmacists, pharmacies, and wholesalers to import qualifying drugs from permitted countries into the United States.''.

(c) LIMITATION.—Section 804(c) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 384(c)) is amended by striking ''prescription drug'' each place it appears and inserting ''qualifying drug''.

(d) INFORMATION AND RECORDS.—Section 804(d)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 384(d)(1)) is amended—

(1) by striking subparagraph (G) and redesignating subparagraphs (H) through (N) as subparagraphs (G) through (M), respectively;

(2) in subparagraph (H) (as so redesignated), by striking ''telephone number, and professional license number (if any)'' and inserting ''and telephone number''; and

(3) in subparagraph (L) (as so redesignated), by striking ''(J) and (L)'' and inserting ''(I) and (K)''.

(e) TESTING.—Section 804(e) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 384(e)) is amended to read as follows:

''(e) TESTING.—The regulations under subsection (b) shall require that the testing described under subparagraphs (I) and (K) of subsection (d)(1) be conducted by the importer of the qualifying drug, unless the qualifying drug is subject to the requirements under section 505C for counterfeit-resistant technologies.''.

(f) REGISTRATION OF EXPORTERS; INSPECTIONS.—Section 804(f) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 384(f)) is amended to read as follows:

''(f) REGISTRATION OF EXPORTERS; INSPECTIONS.—

''(1) IN GENERAL.—Any person that seeks to be a registered exporter (referred to in this subsection as the 'registrant') shall submit to the Secretary a registration that includes the following:

''(A) The name of the registrant and identification of all places of business of the registrant that relate to qualifying drugs, including each warehouse or other facility owned or controlled by, or operated for, the registrant;

''(B) An agreement by the registrant to—

''(i) make its places of business that relate to qualifying drugs (including ware-

houses and other facilities owned or controlled by, or operated for, the exporter) and records available to the Secretary for on-site inspections, without prior notice, for the purpose of determining whether the registrant is in compliance with this Act's requirements;

''(ii) export only qualifying drugs;

''(iii) export only to persons authorized to import the drugs;

''(iv) notify the Secretary of a recall or withdrawal of a qualifying drug distributed in a permitted country to or from which the registrant has exported or imported, or intends to export or import, to the United States;

''(v) monitor compliance with registration conditions and report any noncompliance promptly;

''(vi) submit a compliance plan showing how the registrant will correct violations, if any; and

''(vii) promptly notify the Secretary of changes in the registration information of the registrant.

''(2) NOTICE OF APPROVAL OR DISAPPROVAL.—

''(A) IN GENERAL.—Not later than 90 days after receiving a completed registration from a registrant, the Secretary shall—

''(i) notify such registrant of receipt of the registration;

''(ii) assign such registrant a registration number; and

''(iii) approve or disapprove the application.

''(B) DISAPPROVAL OF APPLICATION.—

''(i) IN GENERAL.—The Secretary shall disapprove a registration, and notify the registrant of such disapproval, if the Secretary has reason to believe that such registrant is not in compliance with a registration condition.

''(ii) SUBSEQUENT APPROVAL.—The Secretary may subsequently approve a registration that was denied under clause (i) if the Secretary finds that the registrant is in compliance with all registration conditions.

''(3) LIST.—The Secretary shall—

''(A) maintain an up-to-date list of registered exporters (including qualifying Internet pharmacies that sell qualifying drugs to individuals);

''(B) make such list available to the public on the Internet site of the Food and Drug Administration and via a toll-free telephone number; and

''(C) update such list promptly after the approval of a registration under this subsection.

''(4) EDUCATION OF CONSUMERS.—The Secretary shall carry out activities, by use of the Internet website and toll-free telephone number under paragraph (3), that educate consumers with regard to the availability of qualifying drugs for import for personal use under this section, including information on how to verify whether an exporter is registered.

''(5) INSPECTION OF IMPORTERS AND REGISTERED EXPORTERS.—The Secretary shall inspect the warehouses, other facilities, and records of importers and registered exporters as often as the Secretary determines necessary to ensure that such importers and registered exporters are in compliance with this section.''.

(g) SUSPENSION OF IMPORTATION.—Section 804(g) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 384(g)) is amended by—

(1) striking ''and the Secretary determines that the public is adequately protected from counterfeit and violative prescription drugs being imported under subsection (b)''; and

(2) by adding after the period at the end the following: ''The Secretary shall reinstate the importation by a specific importer upon a determination by the Secretary that the violation has been corrected and that the importer has demonstrated that further violations will not occur. This subsection shall not apply to a prescription drug imported by an individual, or to a prescription drug shipped to an individual by a qualifying Internet pharmacy.''.

(h) WAIVER AUTHORITY FOR INDIVIDUALS.—Section 804(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 384(j)) is amended to read as follows:

''(j) IMPORTATION BY INDIVIDUALS.—

''(1) IN GENERAL.—Not later than 180 days after the enactment of the Pharmaceutical Market Access Act of 2007, the Secretary shall by regulation permit an individual to import a drug from a

permitted country to the United States if the drug is—

"(A) a qualifying drug;

"(B) imported from a licensed pharmacy or qualifying Internet pharmacy;

"(C) for personal use by an individual, or family member of the individual, not for resale;

"(D) in a quantity that does not exceed a 90-day supply during any 90-day period; and

"(E) accompanied by a copy of a prescription for the drug, which—

"(i) is valid under applicable Federal and State laws; and

"(ii) was issued by a practitioner who is authorized to administer prescription drugs.

"(2) DRUGS DISPENSED OUTSIDE THE UNITED STATES.—An individual may import a drug from a country that is not a permitted country if—

"(A) the drug was dispensed to the individual while the individual was in such country, and the drug was dispensed in accordance with the laws and regulations of such country;

''(B) the individual is entering the United States and the drug accompanies the individual at the time of entry;

''(C) the drug is approved for commercial distribution in the country in which the drug was obtained;

''(D) the drug does not appear to be adulterated; and

''(E) the quantity of the drug does not exceed a 14-day supply.''.

(i) REPEAL OF CERTAIN PROVISIONS.—Section 804 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 384) is amended by striking subsections (l) and (m).

SEC. 5. REGISTRATION FEES.

Subchapter C of chapter VII of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 397f et seq.) is amended by adding at the end the following:

''PART 5—FEES RELATING TO PRESCRIPTION DRUG IMPORTATION

''SEC. 740A. FEES RELATING TO PRESCRIPTION DRUG IMPORTATION.

''(a) REGISTRATION FEE.—The Secretary shall establish a registration fee program under which a registered exporter under section 804 shall be required to pay

an annual fee to the Secretary in accordance with this subsection.

''(b) COLLECTION.—

''(1) COLLECTION ON INITIAL REGISTRATION.—A fee under this section shall be payable for the fiscal year in which the registered exporter first submits a registration under section 804 (or reregisters under that section if that person has withdrawn its registration and subsequently reregisters) in a amount of $10,000, due on the date the exporter first submits a registration to the Secretary under section 804.

''(2) COLLECTION IN SUBSEQUENT YEARS.—After the fee is paid for the first fiscal year, the fee described under this subsection shall be payable on or before October 1 of each year.

''(3) ONE FEE PER FACILITY.—The fee shall be paid only once for each registered exporter for a fiscal year in which the fee is payable.

''(c) FEE AMOUNT.—

''(1) IN GENERAL.—Subject to subsection (b)(1), the amount of the fee shall be determined each year by the Secretary and shall be based on the anticipated costs to the Secretary of enforcing the

amendments made by the Pharmaceutical Market Access Act of 2007 in the subsequent fiscal year.

''(2) LIMITATION.—

''(A) IN GENERAL.—The aggregate total of fees collected under this section shall not exceed 1 percent of the total price of drugs exported annually to the United States by registered exporters under this section.

''(B) REASONABLE ESTIMATE.—Subject to the limitation described in subparagraph (A), a fee under this subsection for an exporter shall be an amount that is a reasonable estimate by the Secretary of the annual share of the exporter of the volume of drugs exported by exporters under this section.

''(d) USE OF FEES.—The fees collected under this section shall be used for the sole purpose of administering this section with respect to registered exporters, including the costs associated with—

''(1) inspecting the facilities of registered exporters, and of other entities in the chain of custody of a qualifying drug;

''(2) developing, implementing, and maintaining a system to determine registered exporters' compliance with the registration conditions under the

Pharmaceutical Market Access Act of 2007, including when shipments of qualifying drugs are offered for import into the United States; and

''(3) inspecting such shipments, as necessary, when offered for import into the United States to determine if any such shipment should be refused admission.

''(e) ANNUAL FEE SETTING.—The Secretary shall establish, 60 days before the beginning of each fiscal year beginning after September 30, 2007, for that fiscal year, registration fees.

''(f) EFFECT OF FAILURE TO PAY FEES.—

''(1) DUE DATE.—A fee payable under this section shall be paid by the date that is 30 days after the date on which the fee is due.

''(2) FAILURE TO PAY.—If a registered exporter subject to a fee under this section fails to pay the fee, the Secretary shall not permit the registered exporter to engage in exportation to the United States or offering for exportation prescription drugs under this Act until all such fees owed by that person are paid.

''(g) REPORTS.—

''(1) FEE ESTABLISHMENT.—Not later than 60 days before the beginning of each fiscal year, the Secretary shall—

''(A) publish registration fees under this section for that fiscal year;

''(B) hold a meeting at which the public may comment on the recommendations; and

''(C) provide for a period of 30 days for the public to provide written comments on the recommendations.

''(2) PERFORMANCE AND FISCAL REPORT.—Beginning with fiscal year 2007, not later than 60 days after the end of each fiscal year during which fees are collected under this section, the Secretary shall submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives a report that describes—

''(A) implementation of the registration fee authority during the fiscal year; and

''(B) the use by the Secretary of the fees collected during the fiscal year for which the report is made.''.

SEC. 6. COUNTERFEIT-RESISTANT TECHNOLOGY.

(a) MISBRANDING.—Section 502 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 352; deeming drugs and devices to be misbranded) is amended by adding at the end the following:

''(x) If it is a drug subject to section 503(b), unless the packaging of such drug complies with the requirements of section 505C for counterfeit-resistant technologies.''.

(b) REQUIREMENTS.—Chapter V of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351 et seq.) is amended by inserting after section 505B the following:

''SEC. 505C. COUNTERFEIT-RESISTANT TECHNOLOGIES.

''(a) INCORPORATION OF COUNTERFEIT-RESISTANT TECHNOLOGIES INTO PRESCRIPTION DRUG PACKAGING.—The Secretary shall require that the packaging of any drug subject to section 503(b) incorporate—

''(1) overt optically variable counterfeit-resistant technologies that are described in subsection (b) and comply with the standards of subsection (c); or

''(2) technologies that have an equivalent function of security, as determined by the Secretary.

''(b) ELIGIBLE TECHNOLOGIES.—Technologies described in this subsection—

''(1) shall be visible to the naked eye, providing for visual identification of product authenticity with-

out the need for readers, microscopes, lighting devices, or scanners;

''(2) shall be similar to that used by the Bureau of Engraving and Printing to secure United States currency;

''(3) shall be manufactured and distributed in a highly secure, tightly controlled environment; and

''(4) should incorporate additional layers of non-visible covert security features up to and including forensic capability.

''(c) STANDARDS FOR PACKAGING.—

''(1) MULTIPLE ELEMENTS.—For the purpose of making it more difficult to counterfeit the packaging of drugs subject to section 503(b), manufacturers of the drugs shall incorporate the technologies described in subsection (b) into multiple elements of the physical packaging of the drugs, including blister packs, shrink wrap, package labels, package seals, bottles, and boxes.

''(2) LABELING OF SHIPPING CONTAINER.—Shipments of drugs described in subsection (a) shall include a label on the shipping container that incorporates the technologies described in subsection (b), so that officials inspecting the packages will be able to determine the authenticity of the shipment. Chain

of custody procedures shall apply to such labels and shall include procedures applicable to contractual agreements for the use and distribution of the labels, methods to audit the use of the labels, and database access for the relevant governmental agencies for audit or verification of the use and distribution of the labels.

''(d) EFFECTIVE DATE.—This section shall take effect 180 days after the date of enactment of the Pharmaceutical Market Access Act of 2007.''.

SEC. 7. PROHIBITED ACTS.

Section 301 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331) is amended by inserting after subsection (k) the following:

''(l) The failure to register in accordance with section 804(f) or to import or offer to import a prescription drug in violation of a suspension order under section 804(g).''.

SEC. 8. PATENTS.

Section 271 of title 35, United States Code, is amended—

(1) by redesignating subsections (h) and (i) as subsections (i) and (j), respectively; and

(2) by inserting after subsection (g) the following:

''(h) It shall not be an act of infringement to use, offer to sell, or sell within the United States or to import into the United States any patented invention under section 804 (21 U.S.C. 384) of the Federal Food, Drug, and Cosmetic Act that was first sold abroad by or under authority of the owner or licensee of such patent.''.

SEC. 9. OTHER ENFORCEMENT ACTIONS.

(a) IN GENERAL.—Section 804 of the Federal Food, Drug, and Cosmetic Act (as amended in section 4) is amended by adding at the end the following:

''(l) UNFAIR OR DISCRIMINATORY ACTS AND PRACTICES.—

''(1) IN GENERAL.—It is unlawful for a manufacturer, directly or indirectly (including by being a party to a licensing or other agreement) to—

''(A) discriminate by charging a higher price for a prescription drug sold to a person in a permitted country that exports a prescription drug to the United States under this section than the price that is charged to another person that is in the same country and that does not export a prescription drug into the United States under this section;

''(B) discriminate by charging a higher price for a prescription drug sold to a person

that distributes, sells, or uses a prescription drug imported into the United States under this section than the price that is charged to another person in the United States that does not import a prescription drug under this section, or that does not distribute, sell, or use such a drug;

''(C) discriminate by denying supplies of a prescription drug to a person in a permitted country that exports a prescription drug to the United States under this section or distributes, sells, or uses a prescription drug imported into the United States under this section;

''(D) discriminate by publicly, privately, or otherwise refusing to do business with a person in a permitted country that exports a prescription drug to the United States under this section or distributes, sells, or uses a prescription drug imported into the United States under this section;

''(E) discriminate by specifically restricting or delaying the supply of a prescription drug to a person in a permitted country that exports a prescription drug to the United States under this section or distributes, sells, or uses a pre-

scription drug imported into the United States under this section;

''(F) cause there to be a difference (including a difference in active ingredient, route of administration, dosage form, strength, formulation, manufacturing establishment, manufacturing process, or person that manufactures the drug) between a prescription drug for distribution in the United States and the drug for distribution in a permitted country for the purpose of restricting importation of the drug into the United States under this section;

''(G) refuse to allow an inspection authorized under this section of an establishment that manufactures a prescription drug that may be imported or offered for import under this section;

''(H) fail to conform to the methods used in, or the facilities used for, the manufacturing, processing, packing, or holding of a prescription drug that may be imported or offered for import under this section to good manufacturing practice under this Act;

''(I) become a party to a licensing or other agreement related to a prescription drug that

fails to provide for compliance with all requirements of this section with respect to such prescription drug or that has the effect of prohibiting importation of the drug under this section; or

"(J) engage in any other action that the Federal Trade Commission determines to discriminate against a person that engages in, or to impede, delay, or block the process for, the importation of a prescription drug under this section.

"(2) AFFIRMATIVE DEFENSE.—It shall be an affirmative defense to a charge that a person has discriminated under subparagraph (A), (B), (C), (D), or (E) of paragraph (1) that the higher price charged for a prescription drug sold to a person, the denial of supplies of a prescription drug to a person, the refusal to do business with a person, or the specific restriction or delay of supplies to a person is not based, in whole or in part, on—

"(A) the person exporting or importing a prescription drug into the United States under this section; or

"(B) the person distributing, selling, or using a prescription drug imported into the United States under this section.

"(3) PRESUMPTION AND AFFIRMATIVE DEFENSE.—

"(A) PRESUMPTION.—A difference (including a difference in active ingredient, route of administration, dosage form, strength, formulation, manufacturing establishment, manufacturing process, or person that manufactures the drug) created after January 1, 2007, between a prescription drug for distribution in the United States and the drug for distribution in a permitted country shall be presumed under paragraph (1)(H) to be for the purpose of restricting importation of the drug into the United States under this section.

"(B) AFFIRMATIVE DEFENSE.—It shall be an affirmative defense to the presumption under subparagraph (A) that—

"(i) the difference was required by the country in which the drug is distributed; or

"(ii) the Secretary has determined that the difference was necessary to im-

prove the safety or effectiveness of the drug.

''(4) EFFECT OF SUBSECTION.—

''(A) SALES IN OTHER COUNTRIES.—This subsection applies only to the sale or distribution of a prescription drug in a country if the manufacturer of the drug chooses to sell or distribute the drug in the country. Nothing in this subsection shall be construed to compel the manufacturer of a drug to distribute or sell the drug in a country.

''(B) DISCOUNTS TO INSURERS, HEALTH PLANS, PHARMACY BENEFIT MANAGERS, AND COVERED ENTITIES.—Nothing in this subsection shall be construed to—

''(i) prevent or restrict a manufacturer of a prescription drug from providing discounts to an insurer, health plan, pharmacy benefit manager in the United States, or covered entity in the drug discount program under section 340B in return for inclusion of the drug on a formulary;

"(ii) require that such discounts be made available to other purchasers of the prescription drug; or

"(iii) prevent or restrict any other measures taken by an insurer, health plan, or pharmacy benefit manager to encourage consumption of such prescription drug.

"(C) CHARITABLE CONTRIBUTIONS.—Nothing in this subsection shall be construed to—

"(i) prevent a manufacturer from donating a prescription drug, or supplying a prescription drug at nominal cost, to a charitable or humanitarian organization, including the United Nations and affiliates, or to a government of a foreign country; or

"(ii) apply to such donations or supplying of a prescription drug.

"(5) ENFORCEMENT.—

"(A) UNFAIR OR DECEPTIVE ACT OR PRACTICE.—A violation of this subsection shall be treated as a violation of a rule defining an unfair or deceptive act or practice prescribed

under section 18(a)(1)(B) of the Federal Trade Commission Act.

''(B) ACTIONS BY THE COMMISSION.—The Federal Trade Commission—

''(i) shall enforce this subsection in the same manner, by the same means, and with the same jurisdiction, powers, and duties as though all applicable terms and provisions of the Federal Trade Commission Act were incorporated into and made a part of this section; and

''(ii) may seek monetary relief threefold the damages sustained.

''(6) ACTIONS BY STATES.—

''(A) IN GENERAL.—

''(i) CIVIL ACTIONS.—The attorney general of a State may bring a civil action on behalf of the residents of the State, and persons doing business in the State, in a district court of the United States of appropriate jurisdiction for a violation of paragraph (1) to—

''(I) enjoin that practice;

''(II) enforce compliance with this subsection;

"(III) obtain damages, restitution, or other compensation on behalf of residents of the State and persons doing business in the State, including threefold the damages; or

"(IV) obtain such other relief as the court may consider to be appropriate.

"(ii) NOTICE.—

"(I) IN GENERAL.—Before filing an action under clause (i), the attorney general of the State involved shall provide to the Federal Trade Commission—

"(aa) written notice of that action; and

"(bb) a copy of the complaint for that action.

"(II) EXEMPTION.—Subclause (I) shall not apply with respect to the filing of an action by an attorney general of a State under this paragraph, if the attorney general determines that it is not feasible to provide the notice described in that subclause be-

fore filing of the action. In such case, the attorney general of a State shall provide notice and a copy of the complaint to the Federal Trade Commission at the same time as the attorney general files the action.

''(B) INTERVENTION.—

''(i) IN GENERAL.—On receiving notice under subparagraph (A)(ii), the Commission shall have the right to intervene in the action that is the subject of the notice.

''(ii) EFFECT OF INTERVENTION.—If the Commission intervenes in an action under subparagraph (A), it shall have the right—

''(I) to be heard with respect to any matter that arises in that action; and

''(II) to file a petition for appeal.

''(C) CONSTRUCTION.—For purposes of bringing any civil action under subparagraph (A), nothing in this subsection shall be construed to prevent an attorney general of a State from exercising the powers conferred on the attorney general by the laws of that State to—

''(i) conduct investigations;

''(ii) administer oaths or affirmations; or

''(iii) compel the attendance of witnesses or the production of documentary and other evidence.

''(D) ACTIONS BY THE COMMISSION.—

''(i) IN GENERAL.—In any case in which an action is instituted by or on behalf of the Commission for a violation of paragraph (1), a State may not, during the pendency of that action, institute an action under subparagraph (A) for the same violation against any defendant named in the complaint in that action.

''(ii) INTERVENTION.—An attorney general of a State may intervene, on behalf of the residents of that State, in an action instituted by the Commission.

''(iii) EFFECT OF INTERVENTION.—If an attorney general of a State intervenes in an action instituted by the Commission, such attorney general shall have the right—

''(I) to be heard with respect to any matter that arises in that action; and

''(II) to file a petition for appeal.

''(E) VENUE.—Any action brought under subparagraph (A) may be brought in the district court of the United States that meets applicable requirements relating to venue under section 1391 of title 28, United States Code.

''(F) SERVICE OF PROCESS.—In an action brought under subparagraph (A), process may be served in any district in which the defendant—

''(i) is an inhabitant; or

''(ii) may be found.

''(G) LIMITATION OF ACTIONS.—Any action under this paragraph to enforce a cause of action under this subsection by the Federal Trade Commission or the attorney general of a State shall be forever barred unless commenced within 5 years after the Federal Trade Commission, or the attorney general, as the case may be, knew or should have known that the cause of action accrued. No cause of action barred under existing law on the effective date of the

Pharmaceutical Market Access Act of 2007 shall be revived by such Act.

''(H) MEASUREMENT OF DAMAGES.—In any action under this paragraph to enforce a cause of action under this subsection in which there has been a determination that a defendant has violated a provision of this subsection, damages may be proved and assessed in the aggregate by statistical or sampling methods, by the computation of illegal overcharges or by such other reasonable system of estimating aggregate damages as the court in its discretion may permit without the necessity of separately proving the individual claim of, or amount of damage to, persons on whose behalf the suit was brought.

''(I) EXCLUSION ON DUPLICATIVE RELIEF.—The district court shall exclude from the amount of monetary relief awarded in an action under this paragraph brought by the attorney general of a State any amount of monetary relief which duplicates amounts which have been awarded for the same injury.

''(7) EFFECT ON ANTITRUST LAWS.—Nothing in this subsection shall be construed to modify, im-

pair, or supersede the operation of the antitrust laws. For the purpose of this subsection, the term 'antitrust laws' has the meaning given it in the first section of the Clayton Act, except that it includes section 5 of the Federal Trade Commission Act to the extent that such section 5 applies to unfair methods of competition.

''(8) MANUFACTURER.—In this subsection, the term 'manufacturer' means any entity, including any affiliate or licensee of that entity, that is engaged in—

''(A) the production, preparation, propagation, compounding, conversion, or processing of a prescription drug, either directly or indirectly by extraction from substances of natural origin, or independently by means of chemical synthesis, or by a combination of extraction and chemical synthesis; or

''(B) the packaging, repackaging, labeling, relabeling, or distribution of a prescription drug.''.

(b) REGULATIONS.—The Federal Trade Commission shall promulgate regulations to carry out the enforcement program under section 804(l) of the Federal Food, Drug, and Cosmetic Act (as added by subsection (a)).

(c) SUSPENSION AND TERMINATION OF EXPORTERS.—Section 804(g) of the Federal Food, Drug, and Cosmetic Act (as amended by section 4(g)) (21 U.S.C. 384(g)) is amended by—

(1) striking ''SUSPENSION OF IMPORTATION.—The Secretary'' and inserting ''SUSPENSION OF IMPORTATION.—

''(1) IN GENERAL.—The Secretary''; and

(2) adding at the end the following:

''(2) SUSPENSION AND TERMINATION OF EXPORTERS.—

''(A) SUSPENSION.—With respect to the effectiveness of a registration submitted under subsection (f) by a registered exporter:

''(i) Subject to clause (ii), if the Secretary determines, after notice and opportunity for a hearing, that the registered exporter has failed to maintain substantial compliance with all registration conditions, the Secretary may suspend the registration.

''(ii) If the Secretary determines that, under color of the registration, the registered exporter has exported a drug that is not a qualifying drug, or a drug that

does not meet the criteria under this section, or has exported a qualifying drug to an individual in violation of this section, the Secretary shall immediately suspend the registration. A suspension under the preceding sentence is not subject to the provision by the Secretary of prior notice, and the Secretary shall provide to the registered exporter involved an opportunity for a hearing not later than 10 days after the date on which the registration is suspended.

''(iii) The Secretary may reinstate the registration, whether suspended under clause (i) or (ii), if the Secretary determines that the registered exporter has demonstrated that further violations of registration conditions will not occur.

''(B) TERMINATION.—The Secretary, after notice and opportunity for a hearing, may terminate the registration under subsection (f) of a registered exporter if the Secretary determines that the registered exporter has engaged in a pattern or practice of violating 1 or more registration conditions, or if on 1 or more occa-

sions the Secretary has under subparagraph (A)(ii) suspended the registration of the registered exporter. The Secretary may make the termination permanent, or for a fixed period of not less than 1 year. During the period in which the registration of a registered exporter is terminated, any registration submitted under subsection (f) by such exporter or a person who is a partner in the export enterprise or a principal officer in such enterprise, and any registration prepared with the assistance of such exporter or such a person, has no legal effect under this section.''.

SEC. 10. AUTHORIZATION OF APPROPRIATIONS.

There are authorized to be appropriated such sums as may be necessary to carry out this Act (and the amendments made by this Act).

○